



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-18-0307; Docket No. CDC-2018-0019]

**Proposed Data Collection Submitted for Public Comment and
Recommendations**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "Gonococcal Isolate Surveillance Project (GISP)". The purpose of GISP is to monitor trends in antimicrobial resistance in *N. gonorrhoeae* strains in the United States in order to establish a scientific basis for the selection of gonococcal therapies and to allow proactive changes to treatment guidelines before widespread resistance and failures of treatment occur.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0019 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain

approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of

appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Gonococcal Isolate Surveillance Project (OMB Control Number 0920-0307, Expiration 2/28/2019) - Revision - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Gonococcal Isolate Surveillance Project (GISP) was created in 1986 to monitor trends in antimicrobial susceptibilities of *N. gonorrhoeae* strains in the United States. Data from GISP are used to establish a scientific basis for the selection of gonococcal therapies and to allow pro-active changes to treatment guidelines before widespread resistance and failures of treatment occur. To increase capacity to detect and monitor resistant gonorrhea and improve the specificity of GISP, this submission is a revision to include collection of additional isolates and data elements.

The Centers for Disease Control and Prevention has designated *N. gonorrhoeae* as one of three "urgent" antibiotic resistance threats in the United States. The CDC is requesting a

three-year OMB approval for this revision, which directly responds to the National Strategy for Combating Antibiotic Resistant Bacteria by improving and strengthening surveillance of antimicrobial resistance through GISP. Additionally, data from GISP will also allow CDC to monitor and evaluate the effectiveness of public health interventions conducted to support the National Strategy for Combating Antibiotic - Resistant Bacteria. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Sentinel site conducting core surveillance	Demographic/ Clinical Data	20	240	11/60	880
Sentinel site conducting enhanced surveillance	Demographic/ Clinical Data	10	840	12/60	1,680
Regional laboratory	Antimicrobial Susceptibility Testing Results	4	3,300	40/60	8,800
Regional laboratory	Control Strain Susceptibility Testing	4	48	5/60	16
Total					11,376

Leroy A. Richardson,
Chief,
Information Collection Review Office,
Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director,
Centers for Disease Control and Prevention.
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